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(54) Title: **PREVENTION AND/OR TREATMENT OF INFLAMMATORY BOWEL DISEASE USING PYY OR AGONISTS THEREOF**

(57) Abstract: **A novel use of PYY or a PYY agonist is disclosed for treating a bowel condition such as inflammatory bowel disease (e.g. ulcerative colitis and Crohn's disease), bowel atrophy, loss of bowel mucosa and loss of bowel mucosal function. The novel use is based on the discovery and demonstration that administration of PYY or a PYY agonist to an animal can protect the colon from injury induced by a hapten known to induce colitis.**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/18657

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 38/16; 31/00
US CL : 424/198.1; 514/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/198.1; 514/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST, STN/BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EL-SALHY et al, Peptide YY in gastrointestinal disorders. Peptides, Feb 2002, Vol. 23, pages 397-402, especially abstract, pages 398-399, and 401.	1-4
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Y		19-22
X	US 5,604,203 A (Balasubramaniam, A.) 18 February 1997 (18.02.1997), column 7.	1, 2, 4
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Y		3, 19-22
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Y	DUMONT et al, Peptide YY derivatives as selective neuropeptide Y/peptide YY Y1 and Y2 agonists devoided of activity for the Y3 receptor sub-type. Brain Res. Mol. Brain Res. October 1994, Vol. 26, Issue 1-2, pages 320-324, especially abstract.	19-22

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B" earlier application or patent published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

29 February 2004 (29.02.2004)

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22 APR 2004

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/18657

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-4 and 19-22

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- (i) The methods of Groups I-III are distinct methods, each having completely different method steps, using different compositions and having completely different outcomes; whereas Groups IV and V are drawn to two entirely different products, a composition comprising a PYY molecule or a PYY agonist and a probiotic bacterium, respectively.
- (ii) The special technical features of Groups I-III are a method of treating a bowel condition comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a patient, a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition, and a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition, respectively, whereas the special technical features in Groups IV and V are a composition comprising a PYY molecule or an agonist of PYY molecule, and a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist, respectively. Since none of the special technical features of the Groups I-V is found in more than one of the inventions, unity of invention is lacking.

Accordingly, Groups I-V are not so linked by the same or a corresponding special technical feature as to form a single general concept.

2. In the absence of any response from the Applicant, this Authority will establish the International Preliminary Search Report based on the main invention. The claims drawn to the main invention are as follows:

Claims 1-4 and 19-22.

- I. Claims 1-4, and 19-22, drawn to a method of treating a bowel condition comprising administering a pharmaceutically active formulation of PYY or a PYY agonist to a patient.
- II. Claims 5-8, 23, and 24, drawn to a method of manufacturing a drug product comprising PYY or an agonist of PYY.
- III. Claims 9 and 10, drawn to a method of identifying a PYY agonist useful for the prevention or treatment of a bowel condition.
- IV. Claims 11-13, 16-18, and 25, drawn to a composition comprising a PYY molecule or an agonist of PYY molecule.
- V. Claims 14 and 15, drawn to a probiotic bacterium comprising a nucleic acid encoding PYY or a PYY agonist.

INTERNATIONAL SEARCH REPORT

PCT/US03/18657

AMENDED CLAIMS

[received by the International Bureau on 22 June 2004 (22.06.04);
original claims 1-25 replaced by amended claims 1-4 (1 page)]

1. A method of treating an intestinal damage comprising the step of administering a pharmaceutically active formulation of PYY or a PYY agonist to a patient in need thereof.
2. The method of claim 1 wherein the intestinal damage is selected from the group consisting of inflammatory bowel disease, bowel atrophy, loss of bowel mucosa, and loss of bowel mucosal function.
3. The method of claim 2 wherein the inflammatory bowel disease is ulcerative colitis.
4. A method of using PYY or an agonist of PYY comprising the steps of: administering PYY or an agonist of PYY to a subject suffering from an intestinal damage selected from the group consisting of inflammatory bowel disease, bowel atrophy, loss of bowel mucosa, and loss of bowel mucosal function.